
	Calling Critical and/or Corrected Values	Department:	Pathology
		Original Effective Date:	12/91
		Revised Date:	June 3, 2019
		Contact:	Laboratory Compliance, QA and Safety
Name and Title: Gregory Pomper, MD, Laboratory Director, Department of Pathology			
Signature: 		Date Approved: 6/12/19	

1) General Policy Statement:

The definition of a critical test is a test or examination that always requires rapid communication of results, whether those results are normal or abnormal. By their nature, some tests can be identified as always critical, as determined by our institution. Other tests may or may not be critical, and only the physician ordering such tests can determine whether such tests are critical. At present, laboratory tests can be ordered "stat." It is anticipated by the ordering physicians that such tests will **not** be called back. Thus, our current "stat" laboratory tests do not equate with a critical tests.

a) **Scope:** All WFBMC Department of Pathology employees, faculty and staff are responsible for complying with this policy.

b) **Responsible Department/Party/Parties:**

- i. Policy Owner: Department of Pathology
- ii. Procedure: Laboratory Compliance, QA and Safety
- iii. Supervision: Department of Pathology Section Managers
- iv. Implementation: Department of Pathology

2) Definitions: For purposes of this Policy, the following terms and definitions apply:

a) **WFBH:** Wake Forest Baptist Medical Center and all affiliated organizations including all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.

b) **Policy:** As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBMC. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.

c) **Critical Value** – a value at such variance with normal as to represent a pathophysiologic state that may be life-threatening unless some action is taken in a very short time for which an appropriate action is possible.

d) **Corrected Value** – any change in a previously reported value.

e) **Urgent Diagnosis**- are considered medical conditions that, in most cases, should be addressed as soon as possible.

f) **Significant/Unexpected Diagnosis**- are considered medical conditions that are clinically unusual, or unforeseen and should be addressed.

3) Policy Guidelines:

A. Critical Value

- 1) The Department of Pathology will notify immediately, by telephone, a responsible nurse, physician assistant, physician, or other healthcare provider (as defined by the CMO) of any test result which must be corrected or any test value that falls outside the established critical limits established for certain tests. Exceptions to this procedure must be agreed to, in writing, by the CLIA Laboratory Director, Chief Medical Officer (CMO), and chief(s) of the involved service(s).
- 2) Critical laboratory results shall be reported within 30 minutes after results are available.
- 3) For inpatients, the alert call may be communicated to the unit charge nurse or the nurse taking care of the patient. The call must be identified as a Critical Value/Corrected Value call.
- 4) For outpatients and Outreach, the physician alert/call(s) should be made to the clinic or practice and given to the responsible nurse, physician assistant, physician, or healthcare provider. For WFBH practices, phone numbers can be found in the intranet and on Wake On-Call. For Outreach, the list of Outreach Phone Numbers is available in the Lab_Shared folder.

For clinics that perform their own point of care testing or have laboratory services provided for them onsite, critical or corrected values may be presented directly to the authorized provider on paper instead of the required alert/call. The laboratory is still responsible for documenting the date and time the information was presented to the provider, the name of the provider the information was given to and the name of the lab staff responsible for the transaction.

- 5) After-hours, the physician alert call(s) should be made to a responsible nurse, physician assistant, physician, or healthcare provider in the clinic or practice. If no one is available, follow the phone message instructions given for after-hours calls.
- 6) Discharged patient physician alert calls should be made to the hospital operator to obtain the name of the person on call for the discharged patient's service.
- 7) For the list of values defined as critical, see **SOP: Critical Laboratory Values**. The list is also published in the Online Test Directory (Pathology Handbook). The link to the WFBH Critical Laboratory Value list is <http://pathoweb01pv:8080/labhandbook/index.html>.
- 8) **Point of Care Testing Results:**
 - Refer to each Point of Care Testing procedure for the critical value of each test.
- 9) **Anatomic Pathology Results:**
 - See **SOP: Communication of Significant or Unexpected Findings**. Certain Surgical Pathology and Cytopathology diagnoses may be considered particularly urgent, significant or unexpected. These are not considered critical values under this policy. Urgent diagnoses are considered medical conditions that, in most cases, should be addressed as soon as possible. Significant, unexpected diagnoses are considered medical conditions that are clinically unusual or unforeseen and should be addressed at some point in the patient's course.

B. Corrected Result

- 1) For ANY change in a previously reported value, follow the same steps above as calling a critical value.

C. Documenting Critical Values or Corrected Results

- 1) When a critical value is obtained, **STOP**. Call the responsible nurse, physician assistant, physician, or healthcare provider. Identify the patient by name and medical record number or use two (2) unique patient identifier. Additional information such as date and time of sample collection should be given as appropriate.
- 2) Any critical value called must be documented in the patient medical record. The person called should be asked to read back the result and patient information to verify accuracy. The caller will append or type in the appropriate verbal verification code (Smart text Code), CTRB (Called To And Read Back By) or any Smart Text Code specific to their department, along with the following information:
 - The date of the call
 - The time of the call
 - The full name of the person you notified and who read back the result(s).
 - The name of the responsible laboratory individual who called the result(s).
- 3) For patients seen in the 3rd floor Cancer Center, Absolute Neutrophil and Platelet Critical value results are printed and hand delivered to the 3rd floor nurses' desk. Append Smart Text Code GTN (Given to Nurse) and/or ANCN (≤ 0.5 Absolute Neutrophils Notification Given to Nurse) to these results. Read back is not required if the report is given in this manner. All other critical values should be called and the appropriate verification code CTRB (Called To And Read Back By) or any Smart Text Code specific to their department must be appended to the result, along with the following information:
 - The date of the call
 - The time of the call
 - The full name of the person you notified and who read back the result(s).
 - The name of the responsible laboratory individual who called the result(s).
- 4) If it is a point of care test performed in the same clinic as the provider, the critical value can be given to the provider on paper. Read back is not required if the result is given in this manner. Critical result documentation is site specific and includes but is not limited to recording in the "Provider Notification" flowsheet in WakeOne, appended as a comment to the result in WakeOne, recording in the "Critical Value Call report Form Sticker" during downtime, recording in a Critical Value Sticker by Outreach, or recording in the Critical Results log sheet. Regardless of how it is documented, it should include the following information:
 - The date the result was given.
 - The time the information was given.
 - The full name of the provider the result was given to.
 - The name of the personnel responsible for the transaction.
- 5) ANY change in a previously reported value must be called to the responsible nurse, physician assistant, physician, or healthcare provider. Read back is required and Smart text Code CTRB (Called To And Read Back By) must be appended to the corrected value along with the following information:

- The date of the call
 - The time of the call
 - The full name of the provider the information was given to.
 - The name of the responsible laboratory individual who gave the result.
- 6) Three (3) attempts should be made to report the critical or corrected results. If you receive no response after 3 attempts, document the attempts by appending all three phone calls along with the numbers and the time last call was made to the reported value.
- 7) After 3 attempts have been made to give the results, contact the section Medical Director between 8am-5pm or the Clinical Pathologist on-call after hours (found from the Wake On-Call).

4) Review/Revision/Implementation

- a) **Review Cycle:** This policy shall be reviewed by Department of Laboratory Medicine and Pathology at least every 2 years from the effective date.
- b) **Office of Record:** After authorization, the Laboratory Compliance, QA and Safety shall house this policy in a policy database and shall be the office of record for this policy.

5) Related Policies

Critical Laboratory Values
Communication of Significant or Unexpected Findings
Critical Results of Tests and Diagnostic Procedures

6) Governing Law or Regulations

- a) COM.30000, COM.30100 and GEN.41316. CAP Accreditation Program, All Common and Laboratory General Checklist, 08.22.2018.
- b) National Patient Safety Goals - NPSG.02.03.01. The Joint Commission E-dition, January 1, 2019.
- c) 493.1291(g) - Standard: Test Report. Clinical Laboratory Improvement Act of 1988 (CLIA), Rev. 166, 02-03-17.

7) Attachments

N/A

8) Revision/Review Dates

12/91, 5/13, 8/18

Review/ Revision Date	Revision	Signature
	1/7/2019	

6/3/2019	<p>Removed references to Critical Value Task Force. Added SOP: Critical Laboratory Values as source where critical values are listed and added link to Online Test Directory where the list is also published. Removed iSTAT Critical Value and Glucometer Action Range Value. Added to refer to each individual POCT procedure for the critical value of each POC test. Updated, in list form, the items that should be included when documenting notification of critical or corrected value in LIS. Added to use 2 unique patient identifier when calling critical value result. Updated date and time of sample collection as additional information to be given as appropriate. Separated the Cancer Center and Point of Care process of documentation of critical value notification. Added instruction to append or type appropriate verbal verification code (Smart Text Code) specific to the department. Added documentation process for Corrected Results. Added to Related Policies section, <i>Critical Laboratory Values and Critical Results of Tests and Diagnostic Procedures</i>. Added CAP and CLIA standards to Governing Regulations. Removed references to attachment - Critical Value Table.</p>	